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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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06/08/2005

Mark Geach

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7590

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EXAMINER

LEITH, PATRICIA A

ART UNIT

PAPER NUMBER

1655

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/524,493	Applicant(s) GEACH, MARK	
	Examiner Patricia Leith	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-57 and 59-69 is/are pending in the application.
- 4a) Of the above claim(s) 47-50, 52 and 62-68 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40-46, 51, 53-57, 59-61 and 69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/17/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/17/09 has been entered.

Status of the Claims

Claims 40-57 and 59-69 are currently pending in the application.

Claims 47-50, 52 and 62-68 remain withdrawn from the merits as being directed toward a non-elected invention.

Claims 40-46, 51, 53-57, 59-61 and 69 were examined on their merits.

Correctly pointed out by Applicants in their most recent response, regretfully, claims 54-56 were inadvertently omitted from the previous rejections. Claims 54-56 are properly rejected herein, *vide infra*.

Claim Objections

Claim 53 is objected to because of the following informalities:

Claim 53 states 'cellulose, gum and or a sugar derivative" which should properly read: "cellulose, gum **and/or** a sugar derivative."

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Appropriate correction is required.

Rejections Removed

The previous rejections have been removed in light of Applicants' most recent amendment to the claim which specifically states that 'all of the astaxanthin is in the form of micelles.' This limitation overcomes the prior art reference of Jacobson et al. because Jacobson et al. taught the emulsification of yeast cells containing astaxanthin. While Jacobson et al. did teach blending, it is not certain that the yeast cells were lysed. Furthermore, closer prior art has been uncovered which anticipates and makes obvious the claimed invention; said prior art being keenly discussed *vide infra*.

Notably, the phrase 'astaxanthin is in the form of micelles' is interpreted to mean that the astaxanthin is encased in micelles by incorporation with an oil and emulsifying, as taught by the Instant specification, and well-known in the art as discussed *infra*.

Applicants' arguments pertaining to the Jacobson et al. reference are thus found persuasive in light of Applicants' most recent amendment.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 40, 41, 42, 43, 44, 45, 51, 53, 59, 60, 61 and 69 are rejected under 35 U.S.C. 102(b) as being anticipated by Asami et al. (US 6,265,450).

Asami et al. (US 6,265,450) taught a drink composition comprising astaxanthin ethylester and in a liquid state (see Example 2, col. 12). The astaxanthin used by

Art Unit: 1655

Asami et al. was clearly provided in suspended oil 'capsules' or otherwise as 'micelles'" as provided by the Vitamin E (oil/fat-soluble vitamin):

Since astaxanthin and/or its ester is insoluble in water, it can be provided in capsules and so forth by suspending in oil either directly or using an emulsifier, astaxanthin and/or its ester can be dissolved in oil, emulsified in an aqueous solution containing surface active agent or polymer and so forth followed by dissolving the resulting emulsion in water, or it can be spray dried and provided in the form of a liquid or powder. Since the solubility of astaxanthin in oil is extremely low, although considerable time is required to dissolve crystals of astaxanthin in oil, the dissolution rate can be increased by using fine crystals. The solubility of astaxanthin also becomes extremely large when heated to 100.degree. C. or above.

On the other hand, esters of astaxanthin are highly soluble in oils, and can be easily dissolved in oils. Examples of such oils include vegetable oils such as soy bean oil, corn oil, rape seed oil, palm oil, olive oil, safflower oil, lemon oil, orange oil, peanut oil and sunflower oil, hardened oils produced by hydrogenating these oils, natural waxes such as lanolin, whale wax and bees wax, animal fats such as beef tallow, pork tallow and butter as well as wheat germ oil **and concentrated vitamin E oil**. In addition, glycerine fatty acid ester, sucrose fatty acid ester, sorbitan fatty acid ester, soy bean phospholipid, propylene glycol fatty acid ester and stearate diglyceride are used as emulsifiers.

(37) In addition, by enclosing astaxanthin and/or its ester using cyclic dextrin (.alpha.-cyclodextrin, .beta.-cyclodextrin and .gamma.-cyclodextrin), a powdered inclusion can be obtained that can be dissolved in water. (col. 9)

Hence, the encapsulation of astaxanthin esters in 'micelles' (formed by oil coating the astaxanthin and emulsifying) was well-known in the art at the time the invention was made.

Art Unit: 1655

It is noted that the Drink of Example 2 contained water-soluble vitamin C and fat-soluble vitamin E which anticipates claim 45. The drink also contained cyclodextrin which is considered a 'sugar derivative' as claimed in claim 53 (cyclodextrin a non-natural compound, is a derivative of dextrose).

Claims 59, 60 and 69 merely recite intended uses for the composition. Because the composition of Asami et al. was not precluded for enriching the diet of a captive species such as fish, the astaxanthin-containing composition of Asami et al. meets the limitations of claims 59 and 60. Because the astaxanthin-containing composition of Asami et al. was clearly a food composition, the Asami et al. patent additionally anticipates claim 69 which recites the intended use of 'feed composition.'

It follows that because the Asami et al. composition was a feed composition, that claim 61 is anticipated since it is incorporated into a feed composition (e.g., Example 2).

Hence, Asami et al. anticipate the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

Art Unit: 1655

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 40, 41, 42, 43, 44, 45, 46, 51, 53, 59, 60, 61 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Asami et al. (US 6,265,450).

Although Asami et al. did not explicitly disclose an example of a composition comprising astaxanthin with a water-soluble carotenoid (i.e., claim 46), they specifically suggested the incorporation of an antioxidant such as beta-carotene (water-soluble carotenoid):

Furthermore, since astaxanthin and/or its ester are easily oxidized and decompose relatively easily in air, it is desirable to add an antioxidant such as vitamin E, vitamin C, glutathione, phytinic acid, catechin, flavoids or .beta.-carotene to the active ingredient of the present invention to inhibit its decomposition. (col. 9)

Hence, the ordinary artisan would have been motivated to add beta-carotene to the astaxanthin-containing food composition in order to stabilize the astaxanthin seeing that Asami et al. clearly taught that beta-carotene was a preferred antioxidant for preventing the oxidation of astaxanthin. Hence, the ordinary artisan clearly would have recognized the advantage of admixing beta-carotene into the food composition to prolong the therapeutic activity of astaxanthin.

Claims 40, 41, 42, 43, 44, 45, 51, 53, 56, 59, 60, 61 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Asami et al. (US 6,265,450) in view of Kearney et al. (US 6,326,040 B1).

Asami et al. did not teach the use of potassium sorbate as a preservative for their beverage composition (i.e., claim 56).

Although Asami et al. did not explicitly disclose an example of a composition comprising potassium sorbate as a preservative, they did explicitly suggest the incorporation of a preservative:

In the case of using the active ingredient of the present invention as a pharmaceutical, it may be administered in any formulation provided oral administration or parenteral administration can be suitably performed, examples of which include injection solutions, parenteral fluid, powders, granules, tablets, capsules, pills, enteric-coated pills, troches, internal medications, suspensions, emulsions, syrups, external medications, fomentations, nasal drops, ear drops, eye drops, inhalants, ointments, lotions, suppositories and enteral nutrients. They may be used either alone or in combination according to the symptoms. **Each of these formulations can be prepared using known**

Art Unit: 1655

adjuvants routinely used in the field of drug preparation technology with the main drug according to the purpose of use in accordance with routine methods, examples of which include vehicles, binders, **preservatives**, oxidation stabilizers, decomposing agents, lubricants and correctives.

In view of Kearney et al. (US 6,326,040 B1), this patent teaches that potassium sorbates are suitable preservatives for vitamin enriched beverage compositions (see Col. 2, lines 22-35).

One of ordinary skill in the art would have been motivated to chose potassium sorbate for the oral beverage astaxanthin-containing composition of Asami et al. seeing that potassium sorbate was a known preservative used in vitamin-containing beverages. Hence, one of ordinary skill in the art would have had a reasonable expectation of success in selecting such a preservative.

Claims 40, 41, 42, 43, 44, 45, 46, 51, 53, 55, 59, 60, 61 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Asami et al. (US 6,265,450) in view of Morgan et al. (US 4,242,366).

The teachings of Asami et al. were discussed *supra*. Asami et al. did not teach the incorporation of monopropylene glycol (propylene glycol) as a stabilizer (i.e., Claim 55). However, it is reiterated that Asami et al. did specifically suggest the incorporation of emulsifiers (see *supra*).

Propylene glycol is a well-known emulsifying agent as disclosed by Morgan et al. (US 4,242,366) (see col. 2, lines 2-6).

Hence, one of ordinary skill in the art would have been motivated to use propylene glycol as an emulsifying agent in the composition of Asami et al. as it would have acted as a functional equivalent to the emulsifying agents as disclosed by Asami et al. Varying types of known, conventional food and beverage additives in foodstuff compositions is deemed obvious considering the skill level of the ordinary artisan concerning conventional food additives. Thus, the substitution of one additive such as an emulsifying agent for another known emulsifying agent is not deemed inventive in nature; but rather, is deemed an obvious step attainable through routine experimentation. The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). Hence, although the reasoning provided by the Examiner for incorporating propylene glycol into the composition of Asami et al. is different than what Applicants intend; that is, Applicants add propylene glycol (monopropylene glycol) as a stabilizer, and the Examiner has provided motivation to add propylene glycol as a substitute emulsifying agent to act as a functional equivalent to the emulsifying agents as disclosed by Asami et al., the motivation and obviousness exists in the art none-the-less and the rejection is thus valid:

Art Unit: 1655

A rejection under 35 U.S.C. ' 103 based upon the combination of references is not deficient solely because the references are combined based upon a reason or technical consideration which is different from that which resulted in the claimed invention. Ex parte Raychem Corp, 17 U.S.P.Q. 2d 1417.

Claims 40, 41, 42, 43, 44, 45, 46, 51, 53, 54, 59, 60, 61 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Asami et al. (US 6,265,450) in view of Todd, Jr. (US 4,999,205).

The teachings of Asami et al. were discussed *supra*. Asami et al. did not teach the incorporation of polysorbate 80 as an emulsifier (i.e., claim 54). However, it is reiterated that Asami et al. did specifically suggest the incorporation of emulsifiers (see *supra*).

Polysorbate 80 was a well-known emulsifier for food products at the time the invention was made according to Todd, Jr. (US 4,999,205) who disclosed the use of polysorbate 80 as an emulsifier in the preparation of diluted foodstuffs containing curcumin (see Col. 1, lines 11-19).

Hence, one of ordinary skill in the art would have been motivated to use polysorbate 80 as an emulsifying agent in the composition of Asami et al. as it would have acted as a functional equivalent to the emulsifying agents as disclosed by Asami

Art Unit: 1655

et al. Varying types of known, conventional food and beverage additives such as emulsifying agents in foodstuff compositions is deemed obvious considering the skill level of the ordinary artisan concerning conventional food additives. Thus, the substitution of one additive such as an emulsifying agent for another known emulsifying agent is not deemed inventive in nature; but rather, is deemed an obvious step attainable through routine experimentation.

Claims 40, 41, 42, 43, 44, 45, 46, 51, 53, 57, 59, 60, 61 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Asami et al. (US 6,265,450) in view of McAskie (US 4,909,138A).

The teachings of Asami et al. were discussed *supra*. Asami et al. did not teach the incorporation of an antioxidant such as butylated hydroxy-toluene into their astaxanthin-containing composition (i.e., claim 57). However, it is reiterated that Asami et al. did specifically suggest the incorporation of antioxidants to preserve the astaxanthin which was known to be subject to oxidation (see *supra*).

Butylated hydroxy-toluene was a known-antioxidant used in food preparations as disclosed by McAskie. Specifically, McAskie disclosed feedstuffs for ruminant animals comprising butylated hydroxy-toluene as an antioxidant to protect against oxidation (see, for example, Col. 4, lines 28- 59).

Art Unit: 1655

Hence, one of ordinary skill in the art would have been motivated to use butylated hydroxy-toluene as an antioxidant in the composition of Asami et al. as it would have acted as a functional equivalent to the antioxidant agents as disclosed by Asami et al. Varying types of known, conventional food and beverage additives such as antioxidants known to be advantageously used in food composition is determined to be a subject of judicious selection; well within the purview of the ordinary artisan at the time the Invention was made skill level and knowledge concerning conventional food additives such as antioxidants to protect degradation of active ingredients.

Claims 40-46, 51, 53-57, 59-61 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Asami et al. (US 6,265,450) in view of Kearney et al. (US 6,326,040 B1) in view of Morgan et al. (US 4,242,366) in view of Todd, Jr. (US 4,999,205) in view of McAskie (US 4,909,138A).

From the above-cited rejections, it naturally follows that all of the claims are rendered obvious over the combination of individually cited references for the same reasons as presented *supra*.

The Supreme court has acknowledged:

When a work is available in one field of endeavor, design incentives and other market forces can prompt variations of it, either in the same field or a different one. **If a person of ordinary skill can implement a predictable variation..103 likely bars its patentability**...if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond that person's

Art Unit: 1655

skill. A court must ask whether the improvement is more than the predictable use of prior-art elements according to their established functions...

...the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results (see *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 U.S. 2007) emphasis added.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

.Conclusion

No claims are allowed.

.Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1655

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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